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specification the Reference to Related Applications is specifically amended to recite the requested claim to priority.

In addition to the petition to amend priority under 37 CFR 1.78(a)(3) applicant is filing a request for correction of inventorship under 37 CFR 1.48(c) by adding Michael Edgerton, Thomas La Rosa and Kristine Hardeman who are the named inventors of application Serial No. 09/865,439. That petition is supported by

- (a) new declarations of all inventors, and
- (b) statements from each person being added as an inventor, i.e. Michael Edgerton, Thomas La Rosa and Kristine Hardeman, that the addition is necessitated by amendment of the claims and that the inventorship error occurred without deceptive intent on the part of those persons.

#### **Amendment to the Claims -**

Applicant requests amendment to the claims as indicated in the attached Listing of Claims. In this regard new dependent claim 14 is directed a plant of claim 6 having recombinant DNA that comprises a promoter operably linked to native corn DNA encoding the protein with the amino acid sequence of SEQ ID NO:2. New independent claim 15 is directed to a recombinant DNA construct comprising a promoter operably linked to native corn DNA encoding the protein with the amino acid sequence of SEQ ID NO:2. Such a recombinant DNA construct was disclosed in this Application as originally filed and in U.S. application Serial No. 09/865,439 where native corn DNA encoding the protein with the amino acid sequence of SEQ ID NO:2 is found in SEQ ID NO:119104.

#### **Objections to the Specification -**

The objection to the specification because the Reference to Related Applications is not the first paragraph is corrected in the following Amendment to the Specification.

The Examiner also objected to the use of the term "MS-Windows" at page 1, line 6 and suggested that it be accompanied by the generic terminology. Applicant has checked the "About Windows" window in the operating system and finds that Microsoft's usage is "MS® Windows" which indicates that the trademark owner is designating "windows" as a generic term. Nonetheless, applicant has added the term "operating system" to the phrase. The Examiner's further advice on this matter will be appreciated.

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The Examiner has noted applicant's citations to several U.S. patent serial numbers on pages 9 to 11 and required a recitation of the status and patent number if granted. These citations have been corrected in the following amendment to the specification where the status of application Serial No. 09/078,972 is indicated as issued U.S. Patent 6,635,806; application Serial No. 09/757,089 is indicated as pending published application US 2004-0216189 A1; provisional application Serial No. 60/435,987 is indicated as pending published application US 2004-0123347 A1; and application Serial No. 09/823,676 is indicated as issued U.S. Patent 6,717,034.

**Objection to the Claims -**

The objection to claims 6 and 7 as requiring insertion of the article "A" is addressed in the amendment to the claims; and the objection to claim 6 and 7 as requiring insertion of the word "plant" is addressed in the amendment to the claims. Withdrawal of these objections is respectfully requested in view of the corrections made to the claims.

**Rejections of Claims under 35 U.S.C. 112, second paragraph -**

Claims 1-7 are rejected as being indefinite in that claims 1, 5, 6, and 7 recite "a consensus amino acid sequence". The examiner's suggestion to change "a" to --the-- is incorporated into the amendment of those claims. Withdrawal of this rejection is respectfully requested in view of the amendment to the claims.

**Rejections of Claims under 35 U.S.C. 112, first paragraph - enablement**

Claims 1-7 stand rejected as failing to comply with the enablement requirement. Applicant traverses the statement that the claims contain subject matter which was not described in such a way as to enable one skilled in the art to make and/or use the invention. The Court of Appeals for the Federal Circuit, a tribunal charged with the judicial supervision of the Patent & Trademark Office, has stated that the issue of enablement involves assessment of whether one of skill in the art could make and use the invention without undue experimentation. See *Adang v. Fischhoff*, 286 F.3d 1346, 1355 (Fed. Cir. 2002) and *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Applicant submits that identifying and isolating DNA encoding Hap3 proteins with the consensus amino acid sequence of SEQ ID NO:8, cloning the coding DNA into a transformation vector, transforming a plurality of plant cells to produce separate transgenic events, regenerating a population of transgenic plants from the cells of separate transgenic

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events, and screening transgenic plants for water-deficit tolerance to practice the claimed methods and identify and use the claimed plants is not a simple task, but it is achievable by a determined person of ordinary skill in the art willing to dedicate the time and resources to accomplishing the task. A person of ordinary skill in the art of identifying DNA for a consensus amino acid sequence and who knows the amino acid sequences of the four homologous Hap3 proteins (SEQ ID NO:2, 3, 6, and 7) and the consensus amino acid sequence of SEQ ID NO:8, has ample information to apply the ordinary skills in querying databases to identify DNA of other homologous proteins and their cognate DNA. A person of ordinary skill in the art of screening transgenic plants for water-deficit tolerance and who knows the water-deficit tolerance screens disclosed by applicant, has ample information to apply the ordinary skills in screening the produced transgenic plants for water-deficit tolerance. The experimentation required is exacting but once performed is routine. The required experimentation is not so indefinite as to be undue. Applicant's specification together with the general high level of skill common in practitioners of the arts of identifying homologous DNA, plant transformation and transgenic plant screening is an adequate template for such enablement. Reconsideration and withdrawal of this Section 112 rejection for lack of enablement is respectfully requested.

In connection with the enablement rejection the Examiner stated in the Office Action at page 5 that the specification describes a

*"transgenic corn plant and a method of producing said transgenic corn plant with a gene encoding a Hap3 protein (SEQ ID NO:2) that confers water-deficit tolerance."*

But, the examiner also alleges in the Office Action at page 6 that

*"the data presented in Tables 1-3 on pages 13 and 14 does not indicate that the transgenic plant transformed with the recombinant DNA construct expressing a gene which encodes for Hap3 protein as defined in SEQ ID NO:2 actually displayed water-deficit tolerance."*

Applicant submits that such data was provided in a spirit of candor to show that the physical characteristics indicating water-deficit tolerance from screens can be marginally changed which requires statistical analysis for indication. Applicant challenges the Examiner's assertion made in the Office Action at page 6 that the

*"difference in plant height of transgenic versus non-transgenic plant under water-deficit stress conditions is less than 1 cm, which does not appear statistically significant."*

Attention is directed to Table 1 which shows the average change in plant height through first water deficit is reported to have a significance value of 0.015 which is, in fact, statistically

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significant. That is, the chances that the change represents a false positive is only 1.5%. Moreover, for a statement that corn plants expressing a Hap3 protein actually displayed water-deficit tolerance reference is made to the last sentence of Example 1 which states

"on average the recovered transgenic plants were significantly greener and healthier than recovered wild type which were more wilted and yellow (indicating senescence)."

The examiner also noted that in although in Example 2 it is reported that the transgenic corn plants are "likely" to show a phenotype, e.g. higher chlorophyll index, more photosynthate production, cooler leaf temperature, higher stomatal conductance, the examiner declared that the specification provided

*"no indication that the transgenic plants actually displayed these phenotypes."*

Applicant traverses this assertion and directs the examiner's attention to the full last sentence of Example 2 which clearly states:

*"The experimental evidence showed that under water deficit conditions transgenic corn plants expressing Hap3 transcription factor of SEQ ID NO:2 were healthier than wild type and exhibited the following phenotypes:*

- (a) likely to have a higher chlorophyll index, e.g. >42 in transgenic plants as compared to <40 in wild type,*
- (b) likely to produce more photosynthate,*
- (c) likely to have cooler leaf temperature, and*
- (d) likely to maintain higher stomatal conductance."*

Applicant submits that a person of ordinary skill in the art of screening plants under field conditions knows that field screening conditions are not controlled but are subject to the whims of nature and that statistical methods are required to identify changes in phenotypes and water-deficit tolerance can be indicated by likelihoods that the water-deficit-tolerant transgenic plant has the noted phenotype as compared to wild type. Thus, a person of ordinary skill would apply those ordinary skills and use the screening criteria disclosed by Applicant to identify water-deficit-tolerant plants by field screening for the phenotypes and selecting from the transgenic plants being screened those having one or more of higher chlorophyll index, more photosynthate production, cooler leaf temperature and higher stomatal conductance than the wild type plants.

In further connection with the enablement rejection the Examiner stated in the Office Action at pages 6-7 that

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*"Applicants have not provided any working example of transgenic plant or a method of producing a transgenic plant comprising introducing an amino acid sequence comprising SEQ ID NO:8 into the genome of a plant to produce water deficit tolerance phenotype."*

Applicant disagrees and submits that the assertion is contradicted by the Examples. The Examiner's attention is specifically directed to Figure 1 which shows that SEQ ID NO:2, 6 and 7 meet the requirement of being amino acid sequences comprising the consensus amino acid sequence of SEQ ID NO:8. Applicant submits that there is no requirement in the law for working examples. Nonetheless, Applicant has, in fact, provided working examples of transgenic plants and methods of making transgenic plants comprising introducing an amino acid sequence comprising SEQ ID NO:8. See Examples 1, 2, 3, 4, 5 and 6.

Moreover, Applicant disagrees with the Examiner's statements in the Office Action at page 7 about protein structure and amino acid changes followed by the statement that

*"neither the state of the art nor Applicant provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error."*

In this regard Applicant submits that a person of ordinary skill in the art understands that a single amino acid sequence can lead to protein inactivation and loss of phenotype and, thus, does not expect that not all variations will be efficacious. A person of ordinary skill in the art also understands that a wide range of substitutions can be made without affecting loss of phenotype. A reasonable amount of trial and error experimentation is routine in the field of biotechnology. Reference is again made to Figure 1 which shows a number of such substitutions including insertions in the consensus amino acid sequence of SEQ ID NO:8. A person of ordinary skill in the art of transgenic plants understands that water-deficit-tolerance is not guaranteed for all cases of exact match to the consensus amino acid sequence, but that *in-planta* screening is also required as taught in the specification and as illustrated in the examples. A person of ordinary skill knows that inoperable embodiments are identified by systematic screening -- hardly what one would call "random trial and error".

Applicant traverses the Examiner's statement in the Office Action at pages 7-8 that

*"Furthermore, in the absence of structure-based function prediction analysis and subsequent experimentation through working examples of transgenic plant, seed or method of producing said transgenic plant with increased tolerance to water-deficit stress conditions, undue experimentation would be required by a skilled artisan to produce such a transgenic plant or seed or use it in a method of producing such*

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*transgenic plant with increased water deficit tolerance comprising introducing a recombinant DNA construct expressing a gene which encodes SEQ ID NO:8."*

The citation of the Genentech v. Novo Nordisk case seems to rebut the rejection inasmuch as the Court stated, in pertinent part:

*"It is true that Genentech argues, that a specification need not disclose what is well known in the art... However, that general oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification that must supply the novel aspects of an invention in order to constitute adequate enablement. 42 USPQ2d 1001, 1005 (Fed Cir --- 1997)*

In the specification Applicant has supplied the novel aspects of the invention, i.e. materials and conditions. As stated above the level of ordinary skill in the art is so advanced that Applicants' disclosure of the Hap3 proteins and the consensus amino acid sequence and the methods for screening for water-deficit tolerance meet the hurdle discussed by the Court in the Genentech v. Novo Nordisk case.

Applicant is puzzled by the Examiner's conclusion expressed in the Office Action at page 8 that

*"The data presented in the specification (see Tables 1-3 on pages 11-14) raises serious doubts whether transgenic plants described in examples 3 and 4 of the specification were actually water-deficit tolerant."*

The data in Tables 1-3 are part of Example 1 illustrating water-deficit tolerant corn plants while Examples 3 and 4 illustrate water-deficit tolerant soybean plants. The Examiner's "serious doubts" about the characteristics of the soybean plants illustrated in Examples 3 and 4 should be allayed by reading Examples 3 and 4. In Example 3 soybean plants were provided with recombinant DNA expressing a Hap3 protein with amino acid of SEQ ID NO:6 which comprises the consensus amino acid sequence of SEQ ID NO:8. Attention is directed to the following statement found in Example 3:

*"In a water-deficit assay transgenic soybean plants exhibited enhanced resistance to water deficit, i.e. less wilting, as compared to wild type soybean plants."*

In Example 4 soybean plants were provided with recombinant DNA expressing a Hap3 protein with amino acid of SEQ ID NO:7 which comprises the consensus amino acid sequence of SEQ ID NO:8. Attention is directed to the following statement found in Example 4:

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*"transgenic soybean plants exhibited enhanced resistance to water deficit as compared to wild type soybean plants. In particular, transgenic plants wilted less, had higher chlorophyll content, had a higher relative water content, had a higher photosynthesis rate, than their gene negative segregants and parental control plants."*

Those statements found in Examples 3 and 4 are essentially declarations by the inventors that the soybean plants were actually water-deficit tolerant. If the Examiner wishes to maintain this rejection base on "serious doubts" about the soybean plants illustrated in Examples 3 and 4, Applicant respectfully requests a different reason than reliance on Tables 1-3 relating to the corn plants illustrated in Example 1. In this regard attention is directed to the guidance provided by the Board of Patent Appeals and Interferences in *Ex parte Chen* which, when reversing an enablement rejection, stated in pertinent part:

*"... (PTO) bears the initial burden of providing reasons for doubting the objective truth of the statements made by appellants as to the scope of enablement. Only when the PTO meets this burden, does the burden shift to appellants to provide suitable evidence indicating that the specification is enabling in a manner commensurate in scope with the protection sought by the claims."* 61 USPQ2d 1025, 1027 (BPAI 2001)

Finally, applicant submits that the Examiner has made assertions about a failure to enable a person of ordinary skill in the art which seems to indicate that the Examiner has a particularly low regard for the level of skill in the art. See *Bayer AG v. Schein Pharms. Inc.*, 64 USPQ2d 1001, 1006 (Fed Cir 2002) in which the Court said that, because an enabling disclosure by definition turns upon the objective understanding of a skilled artisan, the enabling requirement can be met by a reference to the knowledge of one of ordinary skill in the relevant arts. In this regard, Applicant submits that persons of ordinary skill in the arts required to practice the invention have a Ph.D. and post doc experience and are well versed in identifying homologous genes given a representative number of genes and a consensus amino acid sequence. In this regard see *In re Wallach*, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004) where an amino acid sequence was found to support an entire genus of DNA sequences that can encode the amino acid sequence because the state of the art had developed such that it is a routine matter to convert one to the other. See also *In re Grimme*, 274 F.2d 949, 952 (CCPA 1960) where disclosure of single example and statement of scope was sufficient disclosure of a subgenus. And, *In Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) the court explained further that the written description requirement may be satisfied "if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure."

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In view of the above comments rebutting the lack of enablement rejection both in general and in particular response to specific statements made by the Examiner, Applicant respectfully requests reconsideration and withdrawal of the enablement rejection of claims 1-7.

**Rejections of Claims under 35 U.S.C. 112, first paragraph – written description**

Claims 1-7 stand rejected as failing to comply with the written description requirement.

Applicant traverses the Examiner's statement in the Office Action at pages 8-9 that:

*"The claim(s) contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."*

Applicant submits that it is apparent from the various parts of the application, e.g. the summary of the invention, the detailed description of the invention, the figure, and the originally-filed claims, characterize the methods and plants of the claimed subject matter by consensus amino acid sequence and water-deficit tolerance phenotype. The illustrative examples show different transgenic plants having recombinant DNA expressing three distinct Hap3 proteins which comprise the consensus amino sequence of SEQ ID NO:8. The specification including illustrative examples clearly indicate that Applicants did, in fact, have possession of the aspects of the invention as presently claimed at the time the application was filed. Moreover the illustrative examples by themselves contradict the Examiner's statement in the Office Action at page 9 that:

*"The specification does not disclose and correlate structures of different species of genus Hap3 protein having an amino acid sequence identical to a consensus sequence as SEQ ID NO:8."*

In this regard see *Capon v. Eshhar v. Dudas*, 2005 U.S. App. LEXIS 1685, where the CAFC criticized the PTO's application of a "per se" rule relating to nucleotide sequences to satisfy the written description requirement as expressed in the *Lilly* decision, stating in pertinent part:

*"The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge. The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization."*

*"The 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As*

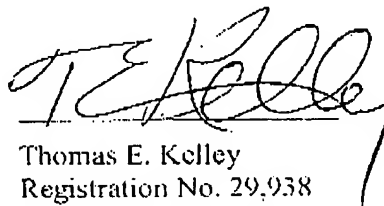


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each field evolves, the balance also evolves between what is known and what is added by each inventive contribution....The Board's requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes."

Applicant submits that what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue. Clearly the state of the art is such that a person of ordinary skill in the art understands that the full scope of genes expressing a Hap3 protein comprising amino acids of the consensus SEQ ID NO:8 covers more than the four illustrative genes but extends to any gene in this narrowly defined class. See also *In re Wallach*, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004) where an amino acid sequence was found to support an entire genus of DNA sequences that can encode the amino acid sequence because the state of the art had developed such that it is a routine matter to convert one to the other. See also *In re Grimme*, 274 F.2d 949, 952 (CCPA 1960) where disclosure of single example and statement of scope was sufficient disclosure of a subgenus. And, *In Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) the court explained further that the written description requirement may be satisfied 'if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.'

In view of the above comments Applicant respectfully requests reconsideration and withdrawal of the written description rejection of claims 1-7 and new dependent claims 14 and 15.



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